

Table 1. Demographic characteristics of the study population	
Age (years)	65.5 ± 1.2
Gender (male/female)	10/10
Education (years)	12.5 ± 0.5
Occupation (white/blue)	10/10
Marital status (married/divorced/widowed)	10/10/0
Smoking status (smoker/non-smoker)	10/10
Alcohol consumption (yes/no)	10/10
Comorbidities (hypertension/diabetes/cholesterol)	10/10/10
Medication (antihypertensive/antidiabetic/anticholesterol)	10/10/10
Family history (hypertension/diabetes/cholesterol)	10/10/10
Physical activity (yes/no)	10/10
Stress level (high/low)	10/10
Social support (yes/no)	10/10
Health status (good/fair/poor)	10/10/10
Quality of life (high/low)	10/10
Life satisfaction (yes/no)	10/10
Overall health (good/fair/poor)	10/10/10
Physical health (good/fair/poor)	10/10/10
Mental health (good/fair/poor)	10/10/10
Social health (good/fair/poor)	10/10/10
Emotional health (good/fair/poor)	10/10/10
Financial health (good/fair/poor)	10/10/10
Environmental health (good/fair/poor)	10/10/10
Overall well-being (good/fair/poor)	10/10/10
Physical well-being (good/fair/poor)	10/10/10
Mental well-being (good/fair/poor)	10/10/10
Social well-being (good/fair/poor)	10/10/10
Emotional well-being (good/fair/poor)	10/10/10
Financial well-being (good/fair/poor)	10/10/10
Environmental well-being (good/fair/poor)	10/10/10
Overall quality of life (good/fair/poor)	10/10/10
Physical quality of life (good/fair/poor)	10/10/10
Mental quality of life (good/fair/poor)	10/10/10
Social quality of life (good/fair/poor)	10/10/10
Emotional quality of life (good/fair/poor)	10/10/10
Financial quality of life (good/fair/poor)	10/10/10
Environmental quality of life (good/fair/poor)	10/10/10
Overall life satisfaction (good/fair/poor)	10/10/10
Physical life satisfaction (good/fair/poor)	10/10/10
Mental life satisfaction (good/fair/poor)	10/10/10
Social life satisfaction (good/fair/poor)	10/10/10
Emotional life satisfaction (good/fair/poor)	10/10/10
Financial life satisfaction (good/fair/poor)	10/10/10
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Overall health status (good/fair/poor)	10/10/10
Physical health status (good/fair/poor)	10/10/10
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Financial health status (good/fair/poor)	10/10/10
Environmental health status (good/fair/poor)	10/10/10
Overall well-being status (good/fair/poor)	10/10/10
Physical well-being status (good/fair/poor)	10/10/10
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Financial quality of life status (good/fair/poor)	10/10/10
Environmental quality of life status (good/fair/poor)	10/10/10
Overall life satisfaction status (good/fair/poor)	10/10/10
Physical life satisfaction status (good/fair/poor)	10/10/10
Mental life satisfaction status (good/fair/poor)	10/10/10
Social life satisfaction status (good/fair/poor)	10/10/10
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Mental well-being status (good/fair/poor)	10/10/10
Social well-being status (good/fair/poor)	10/10/10
Emotional well-being status (good/fair/poor)	10/10/10</

Cognitive Function		Behavioral Function		Quality of Life	
Measure	Score	Measure	Score	Measure	Score
MMSE	24.0	ADL	10.0	QoL	70.0
MoCA	22.0	IADL	8.0	QoL	65.0
BDI-II	15.0	SF-36	50.0	QoL	60.0
PHQ-9	10.0	QoL	55.0	QoL	55.0
SDS	12.0	QoL	50.0	QoL	50.0
STAI	40.0	QoL	45.0	QoL	45.0
STAI	35.0	QoL	40.0	QoL	40.0
STAI	30.0	QoL	35.0	QoL	35.0
STAI	25.0	QoL	30.0	QoL	30.0
STAI	20.0	QoL	25.0	QoL	25.0
STAI	15.0	QoL	20.0	QoL	20.0
STAI	10.0	QoL	15.0	QoL	15.0
STAI	5.0	QoL	10.0	QoL	10.0
STAI	0.0	QoL	5.0	QoL	5.0



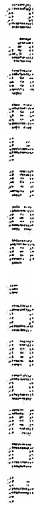
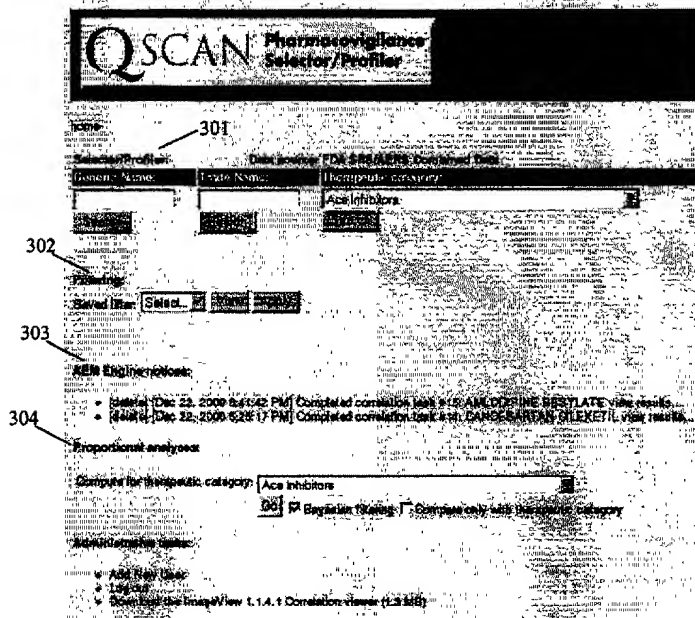
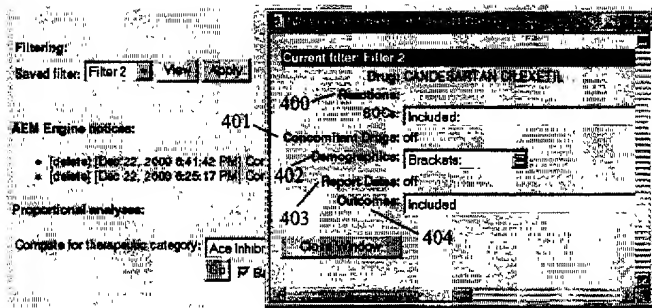
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Figure 3



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Figure 4



FOUO "92672360

Figure 5

home > drug selector

500

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Selected/Profile: Data source: FDA SRS/AERS Combined Data

Generic Name: Trade Name: Therapeutic category:

Filtering:

Saved filter: Select

22 drugs in category: ACE INHIBITORS

Generic Name	Trade Name	Therapeutic Categories	Pedigree
AMLODINE HYDROCHLORIDE	AMLODINE	Ace Inhibitors	
AMLODINE BESYLATE	AMLODIPINE	Ace Inhibitors	
BENAZEPRIL HYDROCHLORIDE	BENAZEPRIL	Ace Inhibitors	
CANDESARTAN CILEXETIL	ATACAND	Ace Inhibitors	
CAPTAPRIL	ACE-HEMMER	Ace Inhibitors	
ENALAPRIL MALEATE	ACETENSIL	Ace Inhibitors	

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Figure 6

Map To	Verbatim	Source	Incidents	Case Count	OEDRx Processing	Cross-reference	First/Last Reported Reactions
PROZAC	PROZAC	SRS	47953	47937		Orange Book	Apr 27 1989/Dec 2 1997
PROZAC	Prozac	AERS	3378	3308	S	Orange Book	Nov 1 1997/Jun 29 1999
FLUOXETINE	FLUOXETINE HYDROCHLORIDE	SRS	2204	2203		NDCD Tradename	Jan 1 1979/Oct 14 1997
FLUOXETINE	Fluoxetine	AERS	574	571	S	NDCD Tradename	Nov 1 1997/Jun 18 1999
PROZAC	Prozac (Fluoxetine Hydrochloride)	AERS	379	378		M Orange Book	Nov 1 1997/Jun 12 1999
PROZAC	Prozac (Fluoxetine)	AERS	140	140		M Orange Book	Nov 7 1997/Apr 24 1999
FLUOXETINE	Fluoxetine Hydrochloride	AERS	122	122	S	Orange Book	Nov 14 1997/Jun 27 1999
FLUOXETINE	Fluoxetine (Fluoxetine Hydrochloride)	AERS	85	85		M Orange Book	Mar 1 1998/Jun 24 1999
FLUOXETINE	Fluoxetine Hcl	AERS	34	34		Orange Book	Nov 1 1997/Nov 1 1998
PROZAC	Prozac (Fluoxetine Hcl)	AERS	20	20		M Orange Book	Nov 1 1997/Mar 12 1999
PROZAC	Prozac (Fluoxetine Hydrochloride)	AERS	17	17		M Orange Book	
FLUOXETINE	Fluoxetine (Fluoxetine)	AERS	15	15		M Orange Book	Nov 15 1997/Jun 6 1999

600 601 602 603 604 605 606 607

703

[illegible]



### Figure 8

Concomitant Drugs		801		802		filter.	
		Non-					
		Suspect suspect					
Top 10 drugs		S	NS	S	NS	Total	%
HYDROCHLOROTHIAZIDE		9	36	0	0	45	10.79%
ASPIRIN		2	38	0	5	45	10.79%
FUROSEMIDE		2	32	0	1	35	8.39%
DIGOXIN		0	30	0	0	30	7.19%
AMLODIPINE BESYLATE		0	24	4	0	28	6.71%
ENALAPRIL MALEATE		4	15	0	5	24	5.76%
VERAPAMIL HYDROCHLORIDE		11	10	0	2	23	5.52%
ESTROGENS, CONJUGATED		0	23	0	0	23	5.52%
METOPROLOL SUCCINATE		8	11	0	3	22	5.28%
METOPROLOL TARTRATE		0	15	0	7	22	5.28%
		Non-					
		Suspect suspect					
Total		Total	Total	Total	Total	Total	Total
		172	1141	1313			

**Figure 9**

900

901

filter

Demographics					
Age Group	Male	Female	Unknown	Total	%
>75	18	73	0	91	21.82%
51-75	89	123	1	213	51.08%
31-50	30	16	0	46	11.03%
16-30	2	1	0	3	0.72%
<16	0	0	0	0	0.00%
Unknown	11	30	23	64	15.35%
Total	150	243	24	417	
%	35.97%	58.27%	5.76%		

more details

FOIA b 7 - D

Figure 10

1000 1001 1002

Report Dates

Timeframe	Count	%
1990-1999	446	100.00%
Total Report Dates		
	446	

more details...

1000 1001 1002

**Figure 11**

1100 1101 filter... 1102

Outcome	Count	%
DEATH	36	7.19%
DISABILITY	16	3.59%
HOSPITALIZATION - INITIAL OR PROLONGED	231	46.11%
LIFE-THREATENING	46	9.18%
OTHER	168	33.53%
REQUIRED INTERVENTION TO PREVENT PERMANENT IMPAIRMENT/DAMAGE	2	0.40%
Total serious outcomes	333	
Total non-serious outcomes	168	
Total outcomes	501	

more details...

FOIA b 7 - DFO

Parameter	Estimate	Standard Error	t-Statistic	p-Value
Intercept	0.00	0.00	0.00	0.00
Age	0.00	0.00	0.00	0.00
Gender	0.00	0.00	0.00	0.00
Marital Status	0.00	0.00	0.00	0.00
Education	0.00	0.00	0.00	0.00
Income	0.00	0.00	0.00	0.00
Health Status	0.00	0.00	0.00	0.00
Living Arrangements	0.00	0.00	0.00	0.00
Employment Status	0.00	0.00	0.00	0.00
Religious Beliefs	0.00	0.00	0.00	0.00
Political Views	0.00	0.00	0.00	0.00
Volunteer Work	0.00	0.00	0.00	0.00
Substance Use	0.00	0.00	0.00	0.00
Mental Health	0.00	0.00	0.00	0.00
Physical Health	0.00	0.00	0.00	0.00
Life Satisfaction	0.00	0.00	0.00	0.00
Overall Well-being	0.00	0.00	0.00	0.00

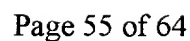


Figure 13

Below are the top 200 correlated terms for your analysis on CANDESARTAN CILEXETIL (Task 95) View with Image View

[Rank]	[Score]	[Term 1]	[Category]	[Term 2]	[Category]
1	7706	Female	Sex	CANDESARTAN CILEXETIL	Target Drug
2	7661	Renal function analyses	Other Reaction	Renal failure and impairment	Other Reaction
3	7244	Paralysis (exc congenital and cranial nerve)	Other Reaction	Central nervous system haemorrhages and cerebrovascular accidents	Other Reaction
4	6901	HOS	Outcome	CANDESARTAN CILEXETIL	Target Drug
5	6888	TRIAMTERENE	Other Drug	DICLOFENAC SODIUM	Other Drug
5	6286	OTH	Outcome	CANDESARTAN CILEXETIL	Target Drug
7	5868	Sex Not Specified	Sex	Age Not Specified	Age
8	5773	VERAPAMIL	Other Drug	TRIAMTERENE	Other Drug
9	5765	HOS	Outcome	Female	Sex
10	5753	Male	Sex	CANDESARTAN CILEXETIL	Target Drug

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# Figure 14

**Correlation Details:**  
**Analyzed Drug:** CANDESARTAN CILEXETIL  
**Cases for term pair:** Renal function analyses [Other Reaction] / Renal failure, and impairment [Other Reaction]

Cases 1 to 18 of 18 cases

Case ID	Sex	Manufacturer Control Code	FDA Report Receipt Date	Age	Drugs	Reactions	Serious
1 3263641	F	19990300088	1999-06-17	74	Atacand	Blood Creatinine Increased; Dialysis Nos; Renal Failure Aggravated	N
2 3198047	F	19990200143	1999-03-12	57	Acuretic, Atorvastatin, Atacand, Cefixime, Nitro-Dur, Terbesmin Expectorante	Blood Creatinine increased; blood Urea increased; Hypotension NOS; Renal Failure Acute	Y
3 3171644	F	19981100002	1999-01-17	69	Xanax, Acetylsalicylic Acid, Wellbutrin, Atacand, Arthrotec, Digoxin, Levaquin, Clantol, Anlvert, Pyndium, Zolof, Dyazide, Verapamil - Slow Release, Ambien	Abdominal Pain Nos, Blood Creatinine Increased; Blood Urea Increased, Coronary Artery Disease Nos, Haemoptysis, Heart Rate Increased, Hypertension Aggravated; Renal Failure Acute	N
4 3270258	F	19990400489	1999-06-26	75	Atacand, Hydrochlorothiazide	Arrhythmia; Atrial Fibrillation; Atrioventricular Block Second Degree; Blood Creatinine Increased; Blood Pressure Decreased; Electrocardiogram ST Segment Depression; Electrocardiogram U Wave Abnormal; Electrolyte Imbalance; Hypokalaemia; Hypocalcaemia; Hyponatraemia; Loss Of Consciousness Nec; Renal Impairment Nos; Syncope	N

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Figure 15

Correlation Details																																								
Analyzed Drug: CANDESARTAN CILEXETIL																																								
Case for Term pair: Renal function analyses [Other Reaction] / Renal failure and impairment [Other Reaction]																																								
1501	Case ID:	3188047																																						
1502	Sex:	Male																																						
1503	Age:	57.0 years, 0.0 months																																						
1504	Reactions:	<table><thead><tr><th>As Reported</th><th>Preferred Term</th><th>High Level Term</th><th>High Level Group Term</th><th>System Organ Class</th></tr></thead><tbody><tr><td>Blood Creatinine Increased</td><td>Blood Creatinine Increased</td><td>Renal function analyses</td><td>Renal and urinary tract investigations and urinalysis</td><td>Investigations</td></tr><tr><td>Blood Urea Increased</td><td>Blood Urea Increased</td><td>Renal function analyses</td><td>Renal and urinary tract investigations and urinalysis</td><td>Investigations</td></tr><tr><td>Hypotension NOS</td><td>Hypotension NOS</td><td>Hypotension</td><td>Decreased and non-specific blood pressure disorders and shock</td><td>Vascular disorders</td></tr><tr><td>Renal Failure Acute</td><td>Renal Failure Acute</td><td>Renal failure and impairment</td><td>Renal disorders (except nephropathies)</td><td>Renal and urinary disorders</td></tr></tbody></table>				As Reported	Preferred Term	High Level Term	High Level Group Term	System Organ Class	Blood Creatinine Increased	Blood Creatinine Increased	Renal function analyses	Renal and urinary tract investigations and urinalysis	Investigations	Blood Urea Increased	Blood Urea Increased	Renal function analyses	Renal and urinary tract investigations and urinalysis	Investigations	Hypotension NOS	Hypotension NOS	Hypotension	Decreased and non-specific blood pressure disorders and shock	Vascular disorders	Renal Failure Acute	Renal Failure Acute	Renal failure and impairment	Renal disorders (except nephropathies)	Renal and urinary disorders										
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1505	Concomitant Drugs:	<table><thead><tr><th>Name</th><th>Dose</th><th>Route</th><th>Suspect</th><th>Status</th></tr></thead><tbody><tr><td>Acuretic</td><td>TAB QD</td><td></td><td>Yes</td><td></td></tr><tr><td>Atorvastatin</td><td></td><td></td><td>No</td><td></td></tr><tr><td>Alacand</td><td>18 MG QD PO ORAL</td><td></td><td>Yes</td><td></td></tr><tr><td>Cefixime</td><td></td><td></td><td>No</td><td></td></tr><tr><td>Niro-Dur</td><td></td><td></td><td>No</td><td></td></tr><tr><td>Terbutalin Expectorante</td><td></td><td></td><td>No</td><td></td></tr></tbody></table>				Name	Dose	Route	Suspect	Status	Acuretic	TAB QD		Yes		Atorvastatin			No		Alacand	18 MG QD PO ORAL		Yes		Cefixime			No		Niro-Dur			No		Terbutalin Expectorante			No	
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Terbutalin Expectorante			No																																					
1506	Outcomes:	HOSPITALIZATION - INITIAL OR PROLONGED (HO) LIFE-THREATENING(LT)																																						
1507	Manufacturer Control Code:	3990200143																																						
1508	Manufacturer Date:	1999-03-5																																						
1509	Adverse Event Date:	1998-12-13																																						
1510	Report Type:	EXP																																						
1511	Report Source:	OTH																																						
1512	Case Source:	AERS																																						
1513	Narrative:																																							

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Table 1. Continued	
1990-1991	1992-1993
1994-1995	1996-1997
1998-1999	2000-2001
2002-2003	2004-2005
2006-2007	2008-2009
2010-2011	2012-2013
2014-2015	2016-2017
2018-2019	2020-2021
2022-2023	2024-2025
2026-2027	2028-2029
2030-2031	2032-2033
2034-2035	2036-2037
2038-2039	2040-2041
2042-2043	2044-2045
2046-2047	2048-2049
2050-2051	2052-2053
2054-2055	2056-2057
2058-2059	2060-2061
2062-2063	2064-2065
2066-2067	2068-2069
2070-2071	2072-2073
2074-2075	2076-2077
2078-2079	2080-2081
2082-2083	2084-2085
2086-2087	2088-2089
2090-2091	2092-2093
2094-2095	2096-2097
2098-2099	2100-2101
2102-2103	2104-2105
2106-2107	2108-2109
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2282-2283	2284-2285
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2414-2415	2416-2417
2418-2419	2420-2421
2422-2423	2424-2425
2426-2427	2428-2

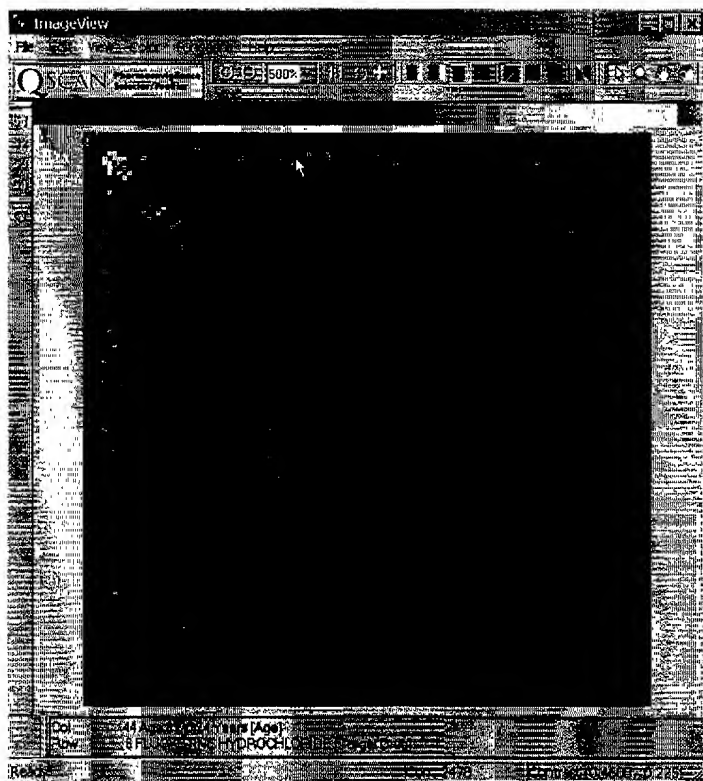
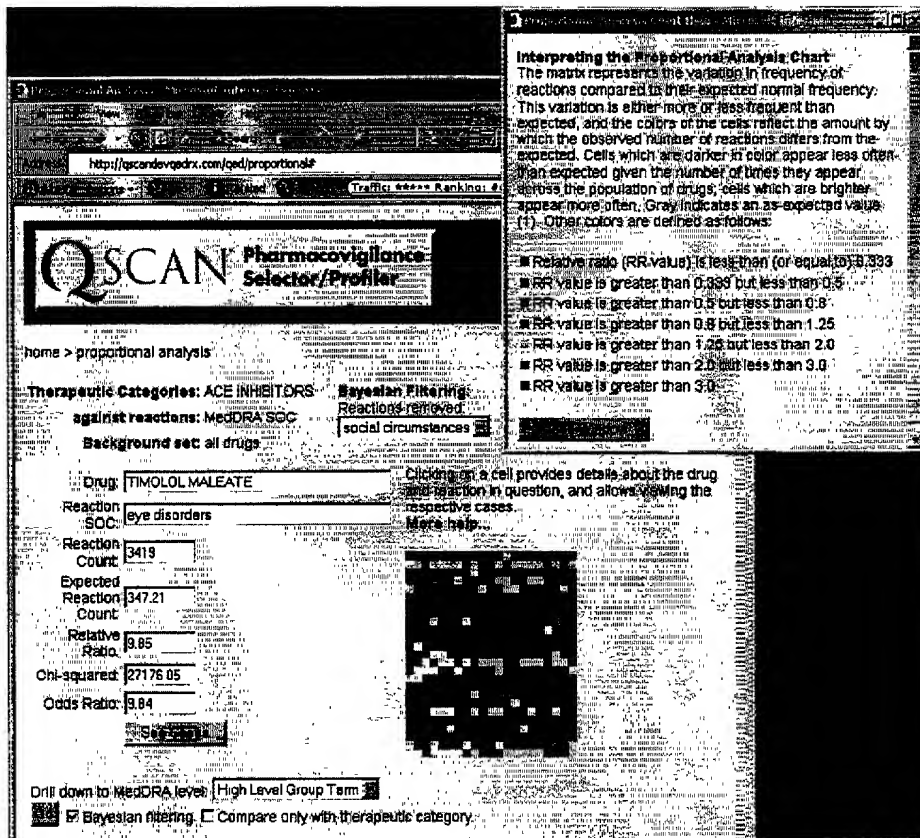


Figure 17



FOUO "SECRET"

Figure 18

Proportional Analysis  
[ACE-INHIBITORS] vs. Reactions (SOCs)  
View by HICUTs

1800	Drug	AMLODIPINE BESYLATE
1801	Reaction	Surgical and medical procedures
1802	Reaction Count	927
1803	Expected Reaction Count	201.02
1804	Relative Ratio	4.61

20250923T1800

# Figure 19

550 entries for this analysis are displayed below.

Correlated Terms		1900	1901	1902	1903	1904
[Reaction]	[Drug]			[Count]	[Expected Count]	[Relative Ratio]
1 6: Eye disorders	19: TIMOLOL MALEATE			3392	346.3	9.8
2 24: Surgical and medical procedures	2: AMLODIPINE BESYLATE			1732	200.4	8.6
3 14: Metabolism and nutrition disorders	1: AMILORIDE HYDROCHLORIDE			838	266.5	3.1
4 24: Surgical and medical procedures	13: METHYLDOPA			37	15.6	2.4
5 16: Neoplasms benign and malignant (including cysts and polyps)	17: RESERPINE			65	28.6	2.3
6 4: Ear and labyrinth disorders	4: CANDESARTAN CILEXETIL			32	14.3	2.2
7 24: Surgical and medical procedures	20: TRANDOLAPRIL			13	6	2.2
8 14: Metabolism and nutrition disorders	18: SPIRONOLACTONE			1330	516.1	2.2

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Table 1. Demographic characteristics of the study population	
Age (years)	65.0 ± 1.5
Gender	
Male	50.0
Female	50.0
Education (years)	12.0 ± 1.0
Marital status	
Married	50.0
Single	50.0
Divorced	50.0
Widowed	50.0
Occupation	
Retired	50.0
Unemployed	50.0
Employed	50.0
Health status	
Good	50.0
Fair	50.0
Poor	50.0
Medication	
Yes	50.0
No	50.0
Comorbidities	
Hypertension	50.0
Diabetes	50.0
Cholesterol	50.0
Smoking	
Yes	50.0
No	50.0
Alcohol consumption	
Yes	50.0
No	50.0
Family size	3.0 ± 1.0
Income (USD/month)	1000.0 ± 200.0
Living alone	50.0
Living with family	50.0
Living in a nursing home	50.0
Living in a community	50.0
Living in a rural area	50.0
Living in an urban area	50.0
Living in a suburban area	50.0
Living in a coastal area	50.0
Living in a mountainous area	50.0
Living in a valley	50.0
Living in a plateau	50.0
Living in a desert	50.0
Living in a forest	50.0
Living in a tundra	50.0
Living in a savanna	50.0
Living in a steppe	50.0
Living in a grassland	50.0
Living in a wetland	50.0
Living in a dryland	50.0
Living in a coastal plain	50.0
Living in a mountain range	50.0
Living in a valley floor	50.0
Living in a plateau top	50.0
Living in a desert floor	50.0
Living in a forest floor	50.0
Living in a tundra floor	50.0
Living in a savanna floor	50.0
Living in a steppe floor	50.0
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Living in a dryland floor	50.0
Living in a coastal plain floor	50.0
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Living in a coastal plain floor floor floor floor floor floor floor	50.0
Living in a mountain range floor floor floor floor floor floor floor	50.0
Living in a valley floor floor	

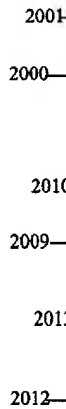


Figure 21

home > drug select > drug profile > case list

Diag: BENZEPAL HYDROCHLORIDE

Reaction SOC: Includes

Concomitant Drugs:

Dyspepsia/Heartburn

Report Date/Ref:

Discontinued:

Summary view: Cases 1 to 50 of 269 cases

6 pages: 1 51 101 151 201 251 2101 2102 2103 2104 2105 2106 2107

Case ID	Sex	Manufacturer (Central Code)	Report Date	Age	Drugs	Reactions	Seizure
1 3510123	F	20001017488E	2000-05-1		Tylenol, Albuterol, Duramorph G-Pm, Aspirin, Acetaminophen Ex-Eid, Anelkin, Latanoprost, Zyrtec, Dacarbazine, Benadryl, Premarin, Lasix, Hclz 25 Mg, Hydrocodone, Immune Globulin Intravenous (Human), Gammanal N 10% - Placido, Iudora, Wykonal, Claritin, Glucophage, Methylprednisolone, Nasonex, Singulair, Proscar, Oxygen Pad, SoluMedrol Pack, Rezulin 200 Mg Am	Cardiac Monitor Nos, Dyspepsia, Dyspnea Nos, Oedema Lower Limb, Pain In Limb, Phlebitis Nos, Physical Examination Nos Abnormal, Rhinorrhea, Tenderness Nos, Venous Thrombosis Deep Limb	Y
2 CD1579035	F	97USA10861	1997-08-1		LOTENSIN	Hypertension NOS, Tablet in stool	N
3 3204355	F	99061573	1993-08-25		Aspirin Coated, Lotensin, Naproxen	Asthma, Dizziness (Exc Vertigo), Dyspepsia, Flushing, Pain Nos	Y
4 CD1455473	F	933544001	1994-05-25		LOTENSIN	Nausea, Vasodilation	N

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